



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/846,658 | 05/01/1997 | JOHN ROBERT ADAIR | CARP-0057 | 9631 |

34132 7590 03/26/2003

COZEN O'CONNER, P.C.
1900 MARKET STREET
PHILADELPHIA, PA 19103-3508

EXAMINER

DAVIS, MINH TAM B

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/26/2003

48

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/846,658

Applicant(s)

ADAIR ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on **12/23/02** has been entered.

Accordingly, claims 24-31 are being examined.

The following are the remaining rejections.

REJECTION UNDER 35 USC 102(e)

Rejection under 35 USC 102(e) of claims 24-31 pertaining to anticipation by Queen et al remains for reasons already of record in paper No.43.

Applicant refers to the earlier response filed on May 20, 2002, stating that Queen patent was not entitled to the dates of its two earliest priority applications, referring to the filing by Queen of several continuation-in-part applications. Applicant recites MPEP 2136.03 which cites *In re Wertheim*, stating that the claims as allowed must be supported in any earlier filed applications for the patent to be effective as a reference as of the filing date of any such earlier application.

Applicant argues that the statements made by Queen during the prosecution of *inter partes* oppositions against the grant of European counterparts of the Queen patent are relevant, since the Queen's European counterparts claim priority to the very same two earlier priority applications. Applicant argues that it is difficult to conceive how the same priority documents fail to support a particular definition in Europe, but support the very same definition in the US.

Applicant further asserts that on page 7 of Exhibit 6, Queen argued that the Patent unequivocally uses the Kabat definition for the framework region, i.e the part of the variable region other than the Kabat CDRs, and that this same definition was given in the priority documents and the application as filed.

Applicant asserts that Queen has acknowledged that his two earlier applications do not support the "Kabat plus Chothia" definition of CDRs used in Queen's issued claims, and thus the Queen patent is not entitled to the dates of those earliest two applications.

The recitation of MPEP 2136.03 and the case law *In re Wertheim* is acknowledged.

Applicant's arguments set forth in paper No.46 have been considered but are not deemed to be persuasive for the following reasons:

It is noted that the limitation "outside the Kabat and Chothia CDRs" is supported in the Queen parent case No: 07/290975 . Since Queen et al in the specification of the parent case No: 07/290975 incorporate by reference the definition of CDR's by Chothia et al, in addition to the CDR's as defined by Kabat (p.8, last paragraph bridging page 9),

one of ordinary skill in the art would have recognized that CDR's as taught by Queen et al would include also CDR's as defined by Chothia et al, besides CDR's as defined Kabat et al, regardless of whether the rest of the specification discloses as examples Kabat's CDR's. In view of the above teaching in of the specification of '975, the remarks of Queen et al during the prosecution of *inter partes* oppositions against the grant of European counterparts of the Queen patent cannot be used to dismiss the teaching of the specification of Queen '975.

It is further noted that the human framework taught by Queen et al is the same as the claimed framework in the instant application (see for example the human framework Eu recited in an example by Queen et al in the prior application '975 on p. 21, first paragraph and by Applicant on p.11, last paragraph, bridging p.12 of the instant specification). In addition, Applicant has not recited any framework that is different from those defined by Kabat et al. Further, Queen et al further teach that a variety of different framework could be used, and could vary by several amino acid substitutions, terminal and intermediate additions and deletions (Queen et al, '975 application, p.12, second paragraph). Queen et al (07/290975, p. 8 last paragraph, bridging p.9) also teach that the variable regions form the antibody binding site, exhibiting conserved framework regions joined by hypervariable regions, which are also called CDR's. Thus from the teaching of Queen et al one would have recognized that the framework region would accommodate the CDRs as defined by Kabat et al or Chothia et al.

In view of the above, the cited Queen patent is entitled to the date of the earliest application '975, and that the claimed invention is anticipated by Queen et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.



SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

MINH TAM DAVIS

March 20, 2003